CATHETER APPLIED IN PERFORATIONS ABOVE THE PAPILLAE IN FISTULA-PAPILLOTOMY

[0001] Field of the Invention

[0002] This invention is the field of medical appliances, more specifically applied in procedures of surgical nature that regard perforations above the papillae in Fistula-papillotomy, with the main objective of obtaining contrasting images through pancreatic biliary.

[0003] Discussion of the Prior Art

[0004] There is a widely diffused and known concept of procedures used in connection with Endoscopic Retrograde Cholangiopancreatography (ERCP), a characteristic caused by the combination of instrumental transpapillary access, making it possible to obtain contrasting images through pancreatic biliary. The procedures named canulization are widely known techniques and the first biliary canulization known in writing occurred in 1968 with Mc Cune as the pioneer. However, it was Kawai who improved the technical details and the accessories of the medical procedure of canulization. For a decade, Endoscopic Retrograde Cholangiopancreatography (ERCP) was predominantly used for diagnostic and contributed in a great proportion for surgical planning.

[0005] In 1974, Classen-Semling and Kawai performed the first endoscopic papillotomy, thus starting the era of therapeutics in pancreatic bile endoscopy. Thus, the diagnostic and therapeutic intentions were applied with the same frequency for more than one decade. At the end of the 1980's and with the intense development of imaging methods, Helical Computerized Tomography and Cholangioresonance was created and the diagnostic aceracea of pancreatic bile illnesses reached the Endoscopic Retrograde Cholangiopancreatography (ERCP). As such, Cholangioendoscopy is predominantly and highly recommended highlighting for therapeutic uses. However, that therapeutic

Endoscopic Retrograde Cholangiopancreatography (ERPC) is related to complications due to manipulation and papillary section.

[0006] Summary of the Invention

[0007] The invention claimed herein can be seen as a treatment similar to the described techniques, with the intention of performing endoscopic procedures over the papilla, causing the least proportion of trauma, thus creating the concept of microtraumatic "papillotomy". In microtraumatic "papillotomy" there is no papillary section, neither any dissipated electric current but a perforation above the papilla is made, characterized by the fistula-papillotomy through perforation. This procedure allows for deep biliary access, making use of a guiding line, pancreatic bile dilatations, passage of prosthesis and finally taking out calculus up to six millimeters (6 mm).

[0008] The procedure, based on the technique of a perforation above the papilla, is performed on patients needing digestive endoscopy, who present a clinical profile with the indication of endoscopic cholangiography. The patients are kept in hospital for 24 hours, which is the minimum amount of time necessary to obtain the laboratory profile trough serial doses of amylase, pypase, RCP and interleucyne-6, before and after 4, 12 and 24 hours of the procedure. Clinical analysis is performed by endoscopists and the presence of abdominal pains is verified in bandages, nausea and vomit to characterize the occurrence of acute pancreatitis. In the event of complications, which are limited, specific measures for each case shall be taken.

[0009] In case of Acute Pancreatitis, the procedures adopted are hospitalization, fasting, hydroelectric restitution, tomographic evaluation and evaluation of the graveness using Ransons's criteria. In case of extensive Submucosa Hematoma after the perforation, the procedures adopted is based on fasting, laboratory and ultrasonic characterization of biliary obstruction. May other complications occur, these will be taken care of appropriately through diverse procedures.

[0010] This application seeks to provide a catheter comprising:(a) a concentric perforating tube attached to a manipulation component on a first extremity and to a needle on a second opposite extremity;(b) a radiopaque mark component externally attached to the needle;(c) a second external concentric tube having a first extremity attached to the manipulation component of the perforation tube and a second opposite extremity; presenting reinforcements placed on the first extremity and second opposite extremity selected from a group consisting of: metal of polymer meshes, spiral metal wires and combination of both; internally bearing the concentric perforation tube, the needle and the radiopaque mark component, and having an external manipulating component adjacent to the manipulation component of the perforation tube;(d) a retraction blockage component externally attached to the second external concentric tube portion, and(e) an Y-shaped connector linearly attached to the manipulating component of the perforating tube.

[0011] This application also seeks to provide a method of using the device.

[0012] Brief description of the Drawings

[0013] FIG. 1 is a representation in perspective view of the device being claimed.

[0014] FIG. 2 represents a side view of the device being claimed, with the needle component exposed.

[0015] FIG. 3 represents a side view of the device being claimed, with the needle component in the resting position.

[0015a] FIG. 4 represents a side view of the device being claimed with the guiding line.

[0016] Detailed description of the Invention

[0017] The main objective involved resides in the evaluation of technical and laboratory profiles of the fistula-papillotomy through perforation above the papilla with subsequent treatment of stent implants by means of endoscopy and/or dilatation with balloons. Thus, the use of the device and method of the present invention seeks to perforate and to create access above the papilla by means of the fistula-papillotomy to view the biliary passages.

[0018] In order to make it possible to reach the objective referred to above, the device of the present invention has a constructive concept based composed of two concentric tube elements that differ in diameter, in which the larger concentric tube has the function of being a guide to the smaller one, which is called concentric perforating tube. The concentric guiding tube possesses greater internal luminosity which makes it possible for the concentric perforating tube to slide within it.

[0019] The internal tube, or concentric perforating tube, is used to perforate, a function that is performed by a needle fastened to it, and shall therefore have an internal diameter that makes it possible for a guiding line (with measures that comply with the procedure) to pass within. Injection of a contrast through the internal luminosity of the concentric perforation tube is also enabled with the device in this invention.

[0020] A component of the Y connector type is connected to its extreme end and the injection of the contrast with a guiding line inserted within it. The functional concept of the product of the catheter type has two opposing steps, the first one corresponding to the non-exposure of the needle. In this position the needle component is located within the concentric guide tube. In the second step, the needle component is exposed, a position ready for the perforation operation.

[0021] The constructive concept of the device also includes a blocking mechanism between the concentric tubes with the function of avoiding the concentric perforating tube to return during the perforating operation, the blocking operation being performed by means of male-female connector elements.

[0022] The device is used together with the endoscope device, inserted through the x canal of the endoscope.

[0023] The catheter of the present invention is generally represented in FIG. 1 by alphabetic reference (A). The Y connecting component (1), has the function of promoting the injection of the contrast, even with the guide line element inserted within its internal luminosity. The catheter is used together with a device of the endoscope type, inserted through the x canal of the latter, where its length shall be sufficiently longer than

the endoscope itself to provide for external manipulation and free length at the extreme ends for the perforating function.

[0024] The set formed by catheter (A) has an external diameter that is smaller than 8 F (French) and is compatible with guiding line (9) 0.035" (see Figure 4).

[0025] A manipulating component of the concentric perforating (2) is defined as a part that is fixed to the near extremity of the concentric perforating tube component (4), with the function of manipulating this tube. Preferably, the manipulating component of the concentric perforating tube (2) has the form of male, female or male/female connectors with standard connections, made in thermoplastic polymers.

[0026] Beside the manipulating function of the concentric perforating tube component (4), the manipulator component of the concentric perforation tube (2) presents a secondary function which is allowing for the blockage of the exposure or retention of the needle component (5).

[0027] The concentric perforation tube component (4), is preferably manufactured in PTFE. The perforation tube is conducted by the inner side of the second external concentric tube component (3), also preferably manufactured in PTFE, composed of material that has properties that facilitate sliding of the concentric perforating tube component (4) within it, being able to support sharp bends without breakage or damage along its extension.

[0028] If necessary, for the regions where critical bends are present, the second external concentric tube component (3) can present reinforcement of other materials, such as metal or polymer meshes, placed at its extreme ends. It is mandatory to have no restrictions to the concentric perforation tube component (4). The second external concentric tube has a first extremity attached to the manipulation component of the perforation tube and a second opposite extremity.

[0029] The kinematics of the mechanism of the catheter device (A) claimed, is based on the sliding of the concentric perforation tube component (4) inside the luminosity of the second external concentric tube component (3), enabling this way the perforating operation.

[0030] The needle component (5), preferably manufactured in steel, is fastened at the far end of the concentric perforation tube (4), while its profile is equal to that of a needle for a perforation operation. It is desirable that the needle component (5) be made of material of sliding properties with a certain rigidity to avoid it be excessively shortened during the perforation. Complementarily, it must be possible for the needle to make sharp bends, because it accompanies the path of the concentric perforation tube component (4), and it shall also have an internal diameter that makes the passage of a guiding line (9) (see Figure 4) of due size possible.

[0031] The device of the present invention also includes a radiopaque marks (6), made in gold, attached to the needle component (5) to view the far end in x-ray, this mark being made in biocompatible radiopaque material.

[0032] A manipulating component (7) of the second external concentric tube is attached to the near end of the second external concentric tube component (3), with the objective of manipulating the tube. Together with the manipulator of the concentric perforation tube (2), it allows for the blockage of the exposure mechanism or the retention of the needle component (5).

[0033] A retraction blockage component (8), with a blockage function restricts the retracting movement of the concentric perforating tube component (4).

[0034] In relation to its functional concept, the catheter device (A) is characterized for presenting a mechanism that uses opposing kinematics between two concentric perforating tube components (4). The first position corresponds to that of non-exposure of the needle component (5), represented through FIG. 3, in that the needle is placed in the inner part of the second external concentric tube component (3). The second position

corresponds to the exposure of the needle component (5), represented by FIG. 2, where it is exposed and ready for the perforating operation.

[0035] To avoid the return of the concentric perforating tube component (4) the retraction blockage component (8) is triggered, avoiding the returning movement of the concentric perforating tube component (4), inside the second external concentric tube component (3), when performing the perforating operation.

[0036] The contrast injection occurs by means of a guiding line (9) (see Figure 4), inserted within the concentric perforating tube component (4). By this means, it is necessary to use an accessory that allows for this type of injection, where Y (1) connector components are used, which are duly connected through manipulator components of the concentric perforation tube (2).

[0037] Essentially, the perforating operation that makes use of the catheter device (A), can occur through the sliding of the concentric perforation tube component (4) within the second external concentric tube component (3). Alternatively, when the catheter device (A) is in the blocking condition, the operator manually uses the catheter device (A) on the surface to be perforated.

[0038] A method of using the catheter comprises the steps of:(i) placing the catheter on the surface of a target(ii) sliding the perforating tube and the needle within the second external concentric tube portion generating a perforation operation on a surface of the target;(iii) access the papilla of a target patient through fistula-papillotomy, and(iv) viewing the biliary passages of the target.

[0039] Alternatively in steps (i) and (ii) the generating a perforation operation is performed by activating the retracting blockage component, placing the catheter on the surface of the target, and performing a perforation manually. The method may further comprise the steps of:(v) attaching a Y-shaped connector attached to the manipulating component of the perforating tube;(vi) injecting a contrast through the guiding line inserted in the internal diameter of the perforating tube.